

40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

A record has been established for this rulemaking under docket number [PP 2E4051/R2136] (including any objections and hearing requests submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Written objections and hearing requests, identified by the document control number [PP 2E4051/R2136], may be submitted to the Hearing Clerk (1900), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, DC 20460.

A copy of electronic objections and hearing requests filed with the Hearing Clerk can be sent directly to EPA at: opp-Docket@epamail.epa.gov

A copy of electronic objections and hearing requests filed with the Hearing Clerk must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all objections and hearing requests submitted directly in writing. The official rulemaking record is the

paper record maintained at the address in ADDRESSES at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a "significant regulatory action" as an action that is likely to result in a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of the Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 18, 1995.

Stephen L. Johnson,
Director, Registration Division, Office of
Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. In § 180.475, by adding new paragraph (c), to read as follows:

§ 180.475 Difenconazole; tolerances for residues.

* * * *

(c) Tolerances are established for difenconazole, [(2*S*,4*R*)/(2*R*,4*S*)]/[(2*R*,4*R*/2*S*,4*S*)] 1-(2-[4-(4-chlorophenoxy)-2-chlorophenyl]-4-methyl-1,3-dioxolan-2-yl-methyl)-1*H*-1,2,4-triazole, in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, grain ¹	0.1
Cattle, fat	0.05
Cattle, meat	0.05
Cattle, mbyp	0.05
Eggs	0.05
Goats, fat	0.05
Goats, meat	0.05
Goats, mbyp	0.05
Hogs, fat	0.05
Hogs, meat	0.05
Hogs, mbyp	0.05
Horses, fat	0.05
Horses, meat	0.05
Horses, mbyp	0.05
Milk	0.01
Poultry, fat	0.05
Poultry, meat	0.05
Poultry, mbyp	0.05
Rye, grain ¹	0.1
Sheep, fat	0.05
Sheep, meat	0.05
Sheep, mbyp	0.05
Wheat, grain	0.1

¹There are no U.S. registrations as of April 12, 1995.

[FR Doc. 95-13248 Filed 5-30-95; 8:45 am]

BILLING CODE 6560-50-F

40 CFR Part 180

[PP 3F4167/R2129; FRL-4952-2]

RIN 2070-AB78

Tebuconazole; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes a tolerance of 0.05 part per million (ppm) for residues of the fungicide tebuconazole (*alpha*-[2-(4-chlorophenyl)-ethyl]-*alpha*-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol) in or on the raw agricultural commodity bananas. Miles, Inc., submitted a petition pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA) for the regulation to establish

a maximum permissible level for residues of the fungicide.

EFFECTIVE DATE: This regulation becomes effective May 31, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 3F4167/R2129], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opdocket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [PP 3F4167/R2129]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in of this document.

FOR FURTHER INFORMATION CONTACT: By mail: Connie B. Welch, Product Manager (PM) 21, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 227, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6900; e-mail: welch.connie@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the **Federal Register** of October 21, 1993 (58 FR 54353), which announced that Miles,

Inc., Agricultural Division (formerly Mobay Corp., Agricultural Chemicals Division), P.O. Box 4913, Kansas City, MO 64120-0013, had submitted pesticide petition (PP) 3F4167 to EPA requesting that the Administrator, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), establish a tolerance for residues of the fungicide tebuconazole (*alpha*-[2-(4-chlorophenyl)-ethyl]-*alpha*-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol) in or on the raw agricultural commodity bananas at 0.05 ppm.

There were no comments received in response to the notice of filing. The scientific data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the tolerance include:

1. A 90-day rat feeding study with a no-observed-effect-level (NOEL) of 34.8 milligrams per kilogram of body weight per day (mg/kg bw/day) (400 ppm) and a lowest-effect-level (LEL) of 171.7 mg/kg bw/day (1,600 ppm) in males, based on decreased body weight gains and histological changes in the adrenals. For females, the NOEL was 10.8 mg/kg bw/day (100 ppm), and the LEL was 46.5 mg/kg bw/day (400 ppm) based on decreased body weights, decreased body weight gains, and histological changes in the adrenals.

2. A 90-day dog feeding study with a NOEL of 200 ppm (73.7 mg/kg bw/day in males and 73.4 mg/kg bw/day in females) and a LEL of 1,000 ppm (368.3 mg/kg bw/day in males and 351.8 mg/kg bw/day in females). The LEL was based on decreases in mean body weights, body weight gains, and food consumption, and an increase in liver *N*-demethylase activity.

3. A 1-year dog feeding study with a NOEL of 1 mg/kg bw/day (40 ppm) and a LEL of 5 mg/kg bw/day (200 ppm), based on lenticular and corneal opacity and hepatic toxicity in either sex (the current Reference Dose was determined based on this study). A subsequent 1-year dog feeding study, using lower doses to further define the NOEL for tebuconazole, defines a systemic LOEL of 150 ppm (based on adrenal effects in both sexes) and a systemic NOEL of 100 ppm.

4. A 2-year rat chronic feeding study defined, a NOEL of 7.4 mg/kg bw/day (100 ppm), and a LEL of 22.8 mg/kg bw/day (300 ppm) based on body weight depression, decreased hemoglobin, hematocrit, MCV and MCHC, and increased liver microsomal enzymes in females. Tebuconazole was not oncogenic at the dose levels tested (0, 100, 300, 1,000 ppm).

5. A rat oral developmental toxicity study with a maternal NOEL of 30 mg/kg bw/day and a LEL of 60 mg/kg bw/day based on elevation of absolute and relative liver weights. For developmental toxicity, a NOEL of 30 mg/kg bw/day and an LEL of 60 mg/kg bw/day was determined, based on delayed ossification of thoracic, cervical and sacral vertebrae, sternum, fore and hind limbs and increase in supernumerary ribs.

6. A rabbit oral developmental toxicity study with a maternal NOEL of 30 mg/kg bw/day and an LEL of 100 mg/kg bw/day based on depression of body weight gains and food consumption. A developmental NOEL of 30 mg/kg bw/day and an LEL of 100 mg/kg bw/day were based on increased post-implantation losses, from both early and late resorptions and frank malformations in eight fetuses of five litters.

7. A mouse oral developmental toxicity study with a maternal NOEL of 10 mg/kg bw/day and an LEL of 20 mg/kg bw/day based on a supplementary study indicating reduction in hematocrit and histological changes in liver. A developmental NOEL of 10 mg/kg bw/day and an LEL of 30 mg/kg bw/day based on dose-dependent increases in runs/dam at 30 and 100 mg/kg bw/day.

8. A mouse dermal developmental toxicity study with a maternal NOEL of 30 mg/kg bw/day and an LEL of 60 mg/kg bw/day based on a supplementary study indicating increased liver microsomal enzymes and histological changes in liver. The NOEL for developmental toxicity in the dermal study in the mouse is 1,000 mg/kg bw/day, the highest dose tested (HDT).

9. A two-generation rat reproduction study with a dietary maternal NOEL of 15 mg/kg bw/day (300 ppm) and a LEL of 50 mg/kg bw/day (1,000 ppm) based on depressed body weights, increased spleen hemosiderosis, and decreased liver and kidney weights. A reproductive NOEL of 15 mg/kg bw/day (300 ppm) and an LEL of 50 mg/kg bw/day (1,000 ppm) were based on neonatal birth weight depression.

10. An Ames mutagenesis study in *Salmonella* that showed no mutagenicity with or without metabolic activation.

11. A micronucleus mutagenesis assay study in mice that showed no genotoxicity.

12. A sister chromatid exchange mutagenesis study using CHO cells that was negative at dose levels 4 to 30 micrograms per milliliter without activation or 15 to 120 micrograms per milliliter with activation.

13. An unscheduled DNA synthesis (UDS) study that was negative for UDS in rat hepatocytes.

Additionally, a mouse oncogenicity study at dietary levels of 0, 20, 60, and 80 ppm for 21 months did not reveal any oncogenic effect for tebuconazole at any dose tested. Because the Maximum Tolerated Dose (MTD) was not reached in this study, the study was classified as supplementary. A followup mouse study at higher doses (0, 500, and 1,500 ppm in the diet), with an MTD at 500 ppm, revealed statistically significant incidences of hepatocellular adenomas and carcinomas in males and carcinomas in females. The initial and followup studies, together with supplementary data submitted by Miles, Inc., were classified as core minimum.

The Office of Pesticide Programs' Health Effects Division's Carcinogenicity Peer Review Committee (CPRC) has classified tebuconazole as a Group C carcinogen (possible human carcinogen). This classification is based on the Agency's "Guidelines for Carcinogen Risk Assessment" published in the **Federal Register** of September 24, 1986 (51 FR 33992). The Agency has chosen to use the reference dose calculations to estimate human dietary risk from tebuconazole residues. The decision supporting classification of tebuconazole as a possible carcinogen (Group C) rather than a probable carcinogen (Group B) was primarily based on the statistically significant increase in the incidence of hepatocellular adenomas, carcinomas, and combined adenomas/carcinomas in both sexes of NMRI mice both by positive trend and pairwise comparison at the HDT, and the structural correlation with at least six other related triazole pesticides that produce liver tumors.

The Reference Dose (RfD) is established at 0.01 mg/kg of body weight (bwt)/day, based on a no-observed-effect level (NOEL) of 1.00 mg/kg bwt/day and an uncertainty factor of 100. The NOEL is based on a 1-year dog feeding study that demonstrated lenticular and corneal opacity and hepatic toxicity as an endpoint effect. The Theoretical Maximum Residue Contribution (TMRC) from the current action is estimated at 0.000019 mg/kg bwt/day and utilizes 0.19% of the RfD for the general population of the 48 States. The TMRCs for the most highly exposed subgroups, children (1 to 6 years old) and children (7 to 12 years old) are 0.000060 mg/kg bwt/day (0.60% of the RfD) and 0.000032 mg/kg bwt/day (0.32% of the RfD), respectively.

The nature of the residue in bananas is adequately understood. An adequate

analytical method using gas chromatography is available for enforcement purposes.

The enforcement methodology has been submitted to the Food and Drug Administration for publication in the Pesticide Analytical Manual, Volume II (PAM II). Because of the long lead time for publication of the method in PAM II, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested from: Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703)-305-5232.

There is no reasonable expectation that secondary residues will occur in milk, eggs, or meat of livestock and poultry since there are no livestock feed items associated with this action.

There are presently no actions pending against the continued registration of this chemical.

Based on the information and data considered, the Agency has determined that the tolerance established by amending 40 CFR part 180 will protect the public health. Therefore, the tolerance is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the **Federal Register**, file written objections to the regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve

one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

A record has been established for this rulemaking under docket number [PP 3F4167/R2129] (including objections and hearing requests submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Written objections and hearing requests, identified by the document control number [PP 3F4167/R2129], may be submitted to the Hearing Clerk (1900), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, DC 20460.

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The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all objections and hearing requests submitted directly in writing. The official rulemaking record is the paper record maintained at the address in **ADDRESSES** at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines "significant" as those actions likely to lead to a rule (1) having an annual effect on the economy of \$100 million or

more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 18, 1995.

Stephen L. Johnson,
Director, Registration Division, Office of
Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. In § 180.474, by amending the table therein by adding and alphabetically inserting an entry for bananas, to read as follows:

§ 180.474 Tebuconazole (alpha-[2-(4-chlorophenyl)-ethyl]-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol); tolerances for residues.

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Commodity			Parts per million

Commodity	Parts per million
Bananas	0.05
* * * *	*

[FR Doc. 95-13251 Filed 5-30-95; 8:45 am]

BILLING CODE 6560-50-F

40 CFR Parts 180 and 186

[PP 8F3646 and FAP 8H5558/R2138; FRL-4955-8]

RIN 2070-AB78

Sethoxydim; Pesticide Tolerance and Feed Additive Regulation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes an increased tolerance for residues of the herbicide sethoxydim (2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one) and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on the raw agricultural commodity sugar beet roots to 1.0 part per million (ppm) and an increase in the established feed additive regulation on the animal feed commodity sugarbeet molasses to 10.0 ppm. The BASF Corp. requested these regulations pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA). These regulations establish the maximum permissible levels for residues of the pesticide in or on the above commodities.

EFFECTIVE DATE: This regulation becomes effective May 31, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 8F3646 and FAP 8H5558/R2138], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401

M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

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FOR FURTHER INFORMATION CONTACT: By mail: Robert J. Taylor, Product Manager, (PM 25), Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 241, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6800; e-mail: taylor.robert@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 12, 1995 (60 FR 18560), EPA issued a proposed rule that gave notice that the BASF Corp., P.O. Box 13528, Research Triangle Park, NC 27709-3528, had submitted a pesticide petition, PP 8F3646, and a feed additive petition, FAP 8H5558, to EPA. PP 8F3646 requests that the Administrator, pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), amend 40 CFR part 180 by establishing a tolerance for the combined residues of the herbicide sethoxydim (2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one) and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on the raw agricultural commodity (RAC) sugarbeet roots at 1.0 part per million (ppm). Feed additive petition (FAP) 8H5558 requests that the Administrator, pursuant to section 409(e) of the FFDCA (21 U.S.C. 348), amend 40 CFR part 186 by establishing a feed additive regulation for the combined residues of the herbicide